

JAN 04 2013

**510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 20, 2012

**1. Company and Correspondent making the submission:**

Name – Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd.

Address – 702/704, Block C, Tsinghua Unis Science Park, No. 13 Langshan Rd, Hi-Tech Industrial Park(north), Nanshan District, Shenzhen City, Guangdong Province

Telephone – +86-755-61869839

Fax – +86-755-61869122

Contact – Mr. Li Peiyong

Email – charliemack@irc-us.com

**2. Device :**

Trade/proprietary name: Body Fat Scale, SF-371

Common Name : Analyzer, Body Fat

Classification Name : Impedance plethysmograph

**3. Predicate Devices :**

Tanita BC-533, (K040778)

**4. Classifications Names & Citations :**

21CFR 870.2770, MNW, Body Fat Analyzer, Class 2

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## 5. Description :

### 5.1 General

The patient steps on the scale device, where four electrodes are located. The patient must step on the electrodes with bare feet, with normal moisture. Through harmless current stimulation of 500  $\mu$ A, at 50 kHz, the Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd. Body Fat Scale calculates the body fat percentage. This calculation is done via the Bioelectrical Impedance Method. The current is passed through the body and the impedance of the body determines the body fat. The calculation is based upon electrical impedance, height, weight, age, and gender. The calculation is performed via internal software, which uses the variables programmed in by the user. There are elements of this process that can produce erroneous readings, such as dry feet or improper-programmed data. The User's Manual defines items which could cause erroneous readings.

### 5.2 Direction

As discussed in the General description, the Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd. Body Fat Scale is relatively simple to use. The user inputs the variable data of age, height, and gender. The user steps onto the scale and the device measures the user weight and body impedance (via the Bioelectric Impedance through the four electrodes on the scale). The scale displays the user's body fat composition. Upon the user's selection, the device can also display the user's weight.

## 6. Indication for use :

The Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd. Body Fat Scale SF-371 measures body weight, and estimates body fat, body water, body muscle mass and body bone mass using BIA (bioelectrical impedance analysis). The device is intended to be used by generally healthy people (from age 16 to age 80) who are not ill, feverish, have a chronic or acute disease, or a condition that affects the level of hydration such as pregnancy.

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7. Comparison with predicate device :

Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd. believes that the Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd. Body Fat Scale is substantially equivalent to the Tanita BC-533 (K040778).

8. Safety and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1. Clinical testing was used to validate the effectiveness and accuracy of the device. All test results were satisfactory.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification TH Leaguer, Inc. concludes that The Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd. Body Fat Scale is safe and effective and substantially equivalent to predicate devices as described herein.

END

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

January 4, 2013

Shenzhen Belter Health Measurement and Analysis Technology Co., Ltd.  
% Mr. Charlie Mack  
Principal Engineer  
IRC  
77325 Joyce Way  
ECHO OR 97826

Re: K122976  
Trade/Device Name: Body Fat Scale, Model SF-371  
Regulation Number: 21 CFR§ 870.2770  
Regulation Name: Impedance plethysmograph  
Regulatory Class: II  
Product Code: MNW  
Dated: December 14, 2012  
Received: December 20, 2012

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K122976

Device Name: Body Fat Scale, Model SF-371

Indications for Use:

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Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S  
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(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and  
Urological Devices

510(k) Number K122976

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